****

*Proposed Regulation/Guidance Document:*

**FDA Draft Guidance for Industry: “Field Alert Report Submission: Questions and Answers.”  
Docket No. FDA-2018-D-2326**

Comments from: ISPE (International Society for Pharmaceutical Engineering)

|  |
| --- |
| **GENERAL COMMENTS ON THE DOCUMENT** |
|  |
|  |
|  |
|  |
|  |
|  |
| Add rows as needed |

**Specific Comments on the Text**

ISPE indicates text proposed for deletion with ~~strikethrough~~ and text proposed for addition with **bold and underlining**.

| **Line Number** | **Current Text** | **Proposed Change** | **Rationale or Comment** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  | Add rows as needed |  |  |